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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,955	01/15/2002	Michael S. Roberts	2370-84	5046

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,955	ROBERTS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-127* is/are pending in the application.

4a) Of the above claim(s) *1-77 and 81-127* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-80* is/are rejected.

7)☒ Claim(s) *78-80* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *January 11, 2005*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The response filed 05/09/06 has been acknowledged. In summery, Claims 1-127 are pending. Claims 78-80 are considered by the examiner. Claims 1-77 and 81-127 are withdrawn from the consideration.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

1. Claim 78 is still rejected under 35 U.S.C. 103(a) as being unpatentable over Martuza et al. (US 5,278,379A) in view of McCormick et al. (US 5, 677,178A).

2. Applicants traverse the rejection although applicants admitted MCF7 breast carcinoma and 5W480 colon tumor cell lines are deficient in interferon-mediated antiviral activity, they are even less sensitive to HSV than the fibroblast cell line Detroit 551 (Martuza et al. see column 20, lines 12-27), Therefore, applicants submit that the reference by Martuza leads away from the present invention, and one of ordinary skill would not have arrived at the present invention based on the breast cancer and colon cancer cell lines described by Martuza et al. Moreover, applicants assert that the reference by McCormick'e reference does not cure such deficiency.

3. Applicants' argument has been fully considered; however, it is not found persuasive because the content of the disclosure on column 20, lines 12-27 does not teach away from the invention. In fact, the entire document teaches a method for testing whether a virus or viral vector has an ability to kill the tumor cell in a tumor or tissue specific manner, wherein the method comprises use of the virus without knowing its susceptibility and cytotoxicity to the test cell lines including the cancer cell line, such as HepG2 being deficiency in interferon mediated antiviral activity and a cell line, such as fibroblastic cell line Detroit 551 having a normal interferon antiviral activity. Therefore, the disclosure of the cited reference teaches all requirements materials, i.e. the interferon deficiency cell line, non-interferon deficiency cell line, and a test virus for running the assay. Moreover, the disclosure of the cited reference, especially the content of column 19 through column 21, teaches a method for evaluating the susceptibility of different test cell lines to the test viruses , which is expressed by susceptibility index (S.I). The

disclosure of Table 3 on column 20 teaches that the HepG2 has a highest susceptibility to the test recombinant herpesviruses , which is 0.9 vs 0.01 of the normal Detroit 551 cell. This difference is more than 5 time sensitive than of the interferon competent cell line, Detroit 551. Therefore, the primary reference does not teach away to the invention. In the contrary, it teaches the same step of the claimed method, except it does not use MOI to measure the virus titer. does not contain the deficiency alleged by the applicants.

4. McCormick'e reference teaches the method of using MOI to measure the virus titer that cure the deficiency of the primary reference of Martuza et al. For example, McCormick teaches measuring the ability of a virus to preferentially infect tumor cells by comparing the multiplicity of infection (MOI) required to kill tumor cells, versus the MOI required to kill non- tumor cells (col. 20, lines 6-2%). One skilled in the art would have appreciated that Martuza et al.'s use of plaguing assays as a measure of oncolysis (col. 20, lines 21-25) could have easily been carried using McCormick's MOI assay. Measuring viral lysis is a matter of routine experimentation and using a plaguing assays or MOI is simply a matter of choice by a skilled in the art absence of unexpected result. To this context, the rejection is maintained.

New ground objection and rejection.

New matter objection

5. The amendment filed May 31, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: in lines 3-4 of claim 78, "a candidate virus is not previously known to possess antineoplastic activity".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 78-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, applicants do not have the possession of the newly amended method for testing a candidate virus that is not previously known to possess antineoplastic activity.

8. In the instant case, the specification clearly define the cited virus in the claims in pages 21-22 should have the characteristic of killing neoplastic cells. The specification cites:" A diverse group of viruses are sued to selectively kill neoplastic cells. Naturally or engineered viruses can functional as an antineoplastic agent. These viruses). Infect neoplastic cells resulting in their death; ii). are replication-competent in the neoplastic cells; and iii). Are limited in killing or normal cells by the antiviral effects of interferon (See lines 20-23 on page 21).

9. All examples used in the specification are the viruses that were known to have oncolytic antineoplastic activity prior to the test.

10. MPEC in 2173.05(i) cites: Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'dmem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP §

2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

11. Because the specification does not have the description for alternative selection of the unknown antineoplastic virus from the positive anti-neoplastic viruses per se, and the mere absence of a positive recitation is not basis for an exclusion according to MPEP, the newly submitted amendment containing the negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BAOQUN LI, MD
PATENT EXAMINER

Bao Qun Li Baoqun Li